



CASE HM/15-21810/A/PCT/DIV

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

Group Art Unit: 1617

WERNER HÖLZL ET AL

Examiner: B. P. Badio

APPLICATION NO: 10/750,810

FILED: DECEMBER 31, 2003

FOR: MICROBICIDAL ACTIVE SUBSTANCES

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

Applicants request review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal and petition for 1 month extension of time.

The review is requested for the reasons stated on the attached sheets.

I am the agent of record for applicants

Reg. No. 31,635

Kevin T. Mansfield

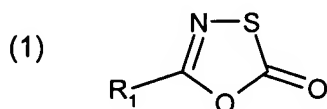
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Claims 1-10, 14-15 and 17 are cancelled and claims 11-13 and 16 are withdrawn. Claims 18 and 19 are finally rejected.

Claims 18 and 19 are directed to a personal care or oral care preparation, comprising from 0.01 to 15 % by weight, based on the total weight of the composition, of a compound of formula



wherein

R₁ is C₁-C₁₆alkyl, C₂-C₁₆alkenyl or C₅-C₈cycloalkyl, each unsubstituted or substituted by halogen, -CN, -NO₂, -C=O, -C=S, -NR₂, -OR₃, -SR₄, -SO₂R₅, -COOR₆ or by a 1,3,4-oxathiazol-2-one radical;

R₂ and R₃ are each independently of the other hydrogen; C₁-C₅alkyl; C₆-C₁₀aryl, or acyl;

R₄ is hydrogen; C₁-C₅alkyl; or C₆-C₁₀aryl;

R₅ is C₁-C₅alkyl; or C₆-C₁₀aryl; and

R₆ is hydrogen; C₁-C₅alkyl; or C₆-C₁₀aryl,

and a cosmetically or orally tolerable adjuvant, respectively. Said compounds are oxathiazol-2-one derivatives.

Claims 18 and 19 are finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Muhlbauer et al. (GB 1,079,348) and Kaminski et al. (U.S. Patent No. 4,115,588) or Lang et al. (U.S. Patent No. 4,772,689) or Blank (U.S. Patent No. 4,847,088) in combination.

Muhlbauer et al. (GB 1079348) disclose the preparation of certain fungicidally active oxathiazol-2-one derivatives which can be used directly as agricultural fungicides, e.g. to prevent mycelial growth of *Corticium rolfsii*, a soil fungus which may cause root rot. Thus the disclosed preparation mentioned in GB is neither a personal care composition nor an oral composition, but rather an agricultural composition.

For *in vitro* testing, solutions containing 1 part of the active substance and 100 to 1000 parts of acetone were placed in agar dishes. Such a solution is used to distribute the active substance in diluted form upon the agar dish. The acetone can volatilize before contact with the fungi cultures. It is not completely clear from the description, but it is believed that the acetone had evaporated from

the agar dish before the contents were contacted with fungal cultures. Otherwise acetone itself might have the effect of preventing mycelial growth of *Corticium rolfsii*. In any event the preparation disclosed in Muhlbauer et al. does not teach or suggest the use of the oxathiazol-2-one derivatives in a personal care or oral composition.

Applicants had urged that the preparation described by Muhlbauer et al. could not be applied to a human body, i.e. used in a personal care or oral composition, and enclosed a 2005 material safety data sheet for acetone from a supplier stating that acetone is a target organ and reproductive toxin. Hence, acetone is not a cosmetically or orally tolerable adjuvant. In addition, Muhlbauer et al. do not provide any suggestion that their preparation could be used for human beings. Responsive thereto the examiner cited 2 references alleged to teach the contrary.

U.S. Patent No. 6,550,080 (Kim et al.) is directed to certain fungicidal compounds having a fluorovinyl- or fluoropropenyl-oxyphenyloxime moiety and stereoisomers thereof. Said compounds have a broad spectrum of fungicidal activity against various plant pathogenic fungi (see column 14, line 66, to column 15, line 7). Col. 15, lines 20-29 describe suitable carriers for this agricultural use, not personal care use. Acetone is mentioned as one fungicidally acceptable carrier. There is however no teaching in this reference that the fungicidal compound mentioned is similar or exchangeable with an oxathiazol-2-one derivative, and there is no teaching that a composition containing oxathiazol-2-one derivatives and acetone as carrier may be used in personal care or oral compositions and may have an advantageous result. This patent claims 1999 priority documents.

U.S. Patent No. 5,833,997 (Mahieu et al.) lists acetone as a solvent commonly use in cosmetic compositions in col. 4, line 49, but doesn't use it. This patent issued in 1998 and claims a 1991 priority date.

However, many substances previously thought to be safe are now known not to be. Many years ago the undersigned worked for 3 months in an industrial lab investigating the vapor phase catalytic air-oxidation of benzene to maleic anhydride. The lab operated for 24 hours a day and reeked of benzene all the time. But no one was concerned because that was before benzene was recognized to be a human carcinogen. Also, it was not too many years ago that virtually all liquid cough syrups contained 0.5% of chloroform, now also considered a carcinogen, and heroin (!) was originally sold for use in children's cough medicines.

Certainly applicants' current reference refutes the very old teaching of Mahieu et al. concerning the suitability of acetone as a solvent in cosmetic compositions. Hence applicants respectfully submit that Muhlbauer's acetone solutions neither teach nor suggest personal care or oral compositions comprising the claimed oxathiazol-2-one derivatives.

Kaminski et al. (U.S. Patent No. 4,115,588) discloses a novel class of N-chloroamino alcohol derivatives which can be used as antibacterial agents in aqueous solutions or in mouthwash, shampoo, soap or other cosmetic preparations (column 17, lines 26 to 48). However the active substance belongs to an entirely different class of chemicals. Without any clear teaching that oxathiazol-2-one derivatives and N-chloroamino alcohol derivatives may be similar or interchangeable with respect to their use in personal care or oral compositions, Kaminski et al. constitutes a very remote state of the art. Indeed the teachings of Muhlbauer et al. and Kaminski et al. are so divergent that their combination is improper *per se*.

Lang et al. (U.S. Patent No. 4,772,689) disclose certain quaternary hydroxy-propyl-substituted chitosan derivatives and cosmetic compositions as set forth in column 2, lines 32 to 49. Lang et al. disclose cosmetic compositions; however the active substance belongs to a different class of chemicals. Without any clear teaching that oxathiazol-2-one derivatives and quaternary hydroxy-propyl-substituted chitosan derivatives may be similar or interchangeable with respect to their use in cosmetic or oral compositions, Lang et al. is also a far remote state of the art.

Blank et al. (U.S. Patent No. 4,847,088) discloses certain synergistic antimicrobial compositions obtainable by combining a silyl quaternary ammonium compound with an acid as set forth in column 2, lines 40 to 62. Surfaces that can be treated include carpet, fabrics, walls, tables, ceilings, and furnishings, especially paper. See column 9, lines 1-8. Blank et al. do not teach personal care or oral compositions. Moreover, without any clear teaching that oxathiazol-2-one derivatives and the combination of a silyl quaternary ammonium compound with an acid may have a similar or interchangeable effect with respect to their use in cosmetic or oral compositions, Blank et al. is also a very remote state of the art.

Re the combination of the above references, each of the cited references (Muhlbauer et al., Kaminski et al., Lang et al., and Blank et al.) teaches the use of a specific class of antimicrobial or fungicidally active substances and the application of compositions containing said substances.


Kaminski et al. and Lang et al. teach that N-chloroamino alcohol derivatives and quaternary hydroxy-propyl-substituted chitosan derivatives can be used in cosmetic or oral compositions, whereas Muhlbauer et al. and Blank et al. teach that oxathiazol-2-one derivatives and the combination of a silane with an acid, respectively, can be used in agriculture or in soft or hard surface compositions.

There is absolutely no teaching in any of these references that an oxathiazol-2-one derivative may be used in a personal care or oral composition. Indeed the teachings of Kaminski et al., Lang et al. and Blank are so divergent from Muhlbauer et al., that their combination is improper *per se*.

Thus the final rejection of claims 18 and 19 under 35 U.S.C. § 103(a) as being unpatentable over Muhlbauer et al. (GB 1,079,348) and Kaminski et al. (U.S. Patent No. 4,115,588) or Lang et al. (U.S. Patent No. 4,772,689) or Blank (U.S. Patent No. 4,847,088) in combination is seen to be in error as to fact and law.

Method of use claims 11-13 and 16 are withdrawn due to a restriction requirement. However the examiner has indicated they will be rejoined if personal care product claims 18 and 19 are allowed and they are of the same scope. Since method of use claims 11-17 are of the same scope with regard to compounds of formula (1), rejoinder is deemed appropriate.

Respectfully submitted,



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Enclosures: notice of appeal, petition for 1 month extension of time, fee letter

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